DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL 13 1998

TRANSMITTED VIA FACSIMILE

Ms. Ellen R. Westrick
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
P.O. Box 4, WP37C-116
West Point, PA 19486

RE: **NDA# 20-829** Singulair (montelukast sodium) Film Coated Tablets
NDA# 20-830 Singulair (montelukast sodium) Chewable Tablet
MACMIS# 6779

Dear Ms. Westrick:

This letter concerns Merck and Company, Inc.'s (Merck) promotional materials for Singulair (montelukast sodium) Film Coated and Chewable Tablets. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the "Singulair AIR (asthma investigator registry) Program promotional material (983594(4)/(6)-02-SNG) as part of its monitoring program. DDMAC has concluded that Merck is disseminating a piece that contains a false or misleading promotional claim in violation of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

Merck's AIR program is a patient questionnaire survey provided to patients by physicians who have prescribed Singulair for their patients. After voluntarily enrolling in the program and before beginning Singulair treatment, the patient is asked to complete a 14 question survey in the physician's office, after which the patient will receive a 4-week free sample of Singulair. The stated objective of the progam is to "provide doctors and patients an opportunity to learn more about important issues related to asthma management." The patient is asked to complete other questionnaires at 4 weeks and 6 months.

The Singulair AIR program materials' cover page and the program's introductory letter to the patient each feature a graphic of a child and an adult running side-by-side. These graphics make a false or misleading representation about the approved use Singulair in exercise-induced bronchospasm. FDA has had previous discussions with Merck on this issue (DDMAC launch letters dated February 18, March 12, and April 1, 1998 regarding promotional materials; and discussions with the Division of Pulmonary Drugs, culminating in a April 2, 1998, labeling supplement regarding sample cartons and containers). On these occasions, Merck was advised that the agency would object to Singulair promotional materials that use images which visually

emphasize individuals involved in exercise/strenuous physical activity because Singulair is not indicated for prevention of exercise-induced bronchospasm (EIB), and thus represent an unapproved use of the product.

Therefore, Merck should immediately cease its use of promotional materials and activities that contain this or similar visual claims. Merck's written response should be received by DDMAC not later than July 27, 1998, listing other violative materials and describing the corrective steps that Merck has taken to ensure that the use of these materials has been suspended. Please direct your response to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Merck that only written communications are considered official.

In all future correspondence, regarding this particular matter, please refer to MACMIS ID # 6271 in addition to the NDA number.

Sincerely,

/S/

Joan Hankin, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications